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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,854	04/06/2006	Piotr Wnukowski	4662-163	8421
23117 7590 09/30/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
MACAULEY, SHERIDAN R				
ART UNIT		PAPER NUMBER		
1651				
MAIL DATE		DELIVERY MODE		
09/30/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,854

Applicant(s)

WNUKOWSKI ET AL.

Examiner

SHERIDAN R. MACAULEY

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/19/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A response and amendment have been received and entered on August 19, 2008. All evidence and arguments have been fully considered. Claim 12 has been cancelled. Claims 1-11 and 13-19 are pending and examined on the merits in this office action.

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 19, 2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-11 and 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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4. The claims are rendered indefinite by the recitation of "the effluents obtained in steps a) and c) to obtain a combined effluent" in step e) of claim 1. It is unclear which effluents this refers to, as there is no effluent recited in steps a) or c).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-11 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corson et al. (US 3,551,203) in view of Dalton (US 2,655,497), and further in view of Shima et al. (EP 0517189 A1). Claim 1 recites a process for purification of a compound comprising an activated carbon treatment, the treatment comprising: a) providing a filter unit containing activated carbon immobilized in a cartridge, wherein the cartridge is a self-contained replaceable entity comprising powdered activated carbon immobilized in a matrix which is in the form of a membrane sheet; b) passing a first volume of a feed containing the compound over a first series of n connected filter units operating in series to obtain a first effluent, wherein n is at least two, said filter units having been assigned a position number 1 to n in the series and position number 1 being the first supplied with the feed, c) disconnecting a filter unit from the first series of filter units at any position number between 1 to n-1 after passing the first volume of feed, and connecting a fresh filter unit at any position that has a higher number than the position number of the disconnected filter unit, resulting in a next series of filter units, d) passing a second volume of feed containing the compound over the next series of filter units to obtain a second effluent, e) optionally combining the effluents obtained in a) and c) to obtain a combined effluent, and f) recovering the compound from the effluent. Claims 2-4 recite the method of claim 2 wherein the filter is disconnected at a position between 1 and n-1, specifically 1, and the fresh filter is connected at position n+1. Claim 5 recites that the treatment of claim 1 is done in

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batch, continuous, or semi-continuous mode. Claims 6, 8 and 9 recite that the flow rate in the process of claim 1 is 0.05 to 400 L/min, that the flux is 1 to 50 liters per meter squared per minute. Claim 7 recites that the cartridge of claim 1 is a self-contained replaceable entity comprising powdered activated carbon immobilized in a matrix that is the form of a membrane sheet. Claim 10 recites that the process of claim 1 is operated at a temperature from a 10 to 40 degrees C. Claim 11 recites that the disconnected filter is regenerated in situ by rinsing with a solvent. Claims 13, 14 and 18 recite that the compound of claim 1 is a secondary metabolite or a protein, specifically an antibiotic, vitamin, carotenoid or PUFA, specifically cluvulanic acid, streptomycin, chloramphenicol, tetracycline or beta-carotene. Claims 15-17 recite the process of claim 1 wherein the compound is obtained by fermentation using a microorganism, particularly a *Streptomyces* species, specifically *S. clavuligerus*, *S. griseus*, *S. venezuela*, *S. jumonjinesis*, *S. katsurahamanus*, or *S. aureofaciens*. Claim 19 recites the process of claim 1 further comprising the step of converting the compound into a pharmaceutically acceptable salt or food grade product.

9. Corson teaches a process for purification of a compound (dextrose) comprising an activated carbon treatment using a filter unit containing activated carbon immobilized in a matrix (a filter), the treatment comprising: passing feed containing the compound over a first series of connected filter units operating in series to obtain an effluent; disconnecting an upstream filter unit from the first series of filter units and connecting a downstream filter unit; passing a next volume of feed containing the compound over the filter unit; and recovering the compound (col. 8, lines 1-14, col. 9, lines 22-34). In the

process of Corson, the first filter in the series is disconnected and the fresh filter which is connected is the last filter in the series (col. 9, lines 22-34). Corson teaches the use of 2 to 5 filters in series (col. 3, lines 49-50). The process of Corson may be operated in batch mode (col. 8, lines 1-14). Corson teaches that the flux is 5 to 40 gallons per hour per square feet of filter, which is equal to 3.4 to 27 liters per minute per square meters (col. 4, lines 56-65). The dextrose purified by Corson could be considered an unstable compound. Corson teaches that the method may be operated at room temperature, which would be between 10 and 40 degrees C (col. 5, lines 41-42). Corson teaches that the filter may be regenerated using solvents (col. 5, lines 50-56).

10. Corson does not specifically teach that the process is carried out at the claimed flow rate or with the claimed residence time within a filter. Corson does not teach the regeneration of the disconnected filter in situ. Corson does not teach that the compound is a secondary metabolite or protein, specifically not those recited in the claims, or that the compound is obtained by microbial fermentation, particularly not with the claimed *Streptomyces*. Corson does not specifically teach the conversion of the compound into a pharmaceutical or food grade product. Corson also does not teach that the filter is a cartridge that is a self-contained replaceable entity comprising powdered activated carbon immobilized in a matrix.

11. Dalton teaches a process for the purification of streptomycin from a solution resulting from the microbial fermentation of *Streptomyces griseus* (col. 1, lines 22-32, col. 5, example 1). Dalton teaches that the purification of streptomycin is effected by passing the solution through a filter comprising activated carbon (col. 1, lines 22-32).

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12. Shima teaches a sheet containing activated carbon fiber that can be put into a filter cartridge that is a self-contained replaceable entity for the filtration of liquids (abstract, p. 5, line 56-p. 6, line 7).

13. At the time of the invention, a process for carrying out activated carbon filtration for the recovery of a compound using the claimed series of filters was known, as taught by Corson. It was also known at the time of the invention that streptomycin obtained by microbial fermentation could be purified using an activated carbon filter, as taught by Dalton. A cartridge containing immobilized activated carbon for the separation of treatment of fluids was also known, as taught by Shima. Although the references do not specifically disclose the downstream processing of the compounds into pharmaceutical or food grade products, one of ordinary skill in the art would recognize that both dextrose and streptomycin are desirable components of pharmaceutical or food products; one would thus be motivated to produce pharmaceutical or food grade products from the compounds purified by these methods. One of ordinary skill in the art would have been motivated to combine the teachings of Corson and Dalton because Dalton teaches that the use of activated carbon with a small mesh size can result in clogging of the filter (col. 2, lines 10-15). Corson teaches a method whereby filters may be taken out of operation and replaced by fresh filters. One of ordinary skill in the art would therefore have recognized that it would have been advantageous to use the filtration method of Corson to purify streptomycin by the method of Dalton. One of ordinary skill in the art would have been motivated to use the filter of Shima in the combined method because Shima teaches that the immobilized carbon sheets are more

effective than granular activated carbon filters because they have a higher rate of adsorption and desorption and that the sheets disclosed in the reference can be housed in a container without being damaged (p. 2, lines 2-6 and 37-42). Although Corson does not specifically teach the claimed flow rate or the claimed residence time, one of ordinary skill would recognize that the filter size could be selected by routine experimentation, and it would be likely that one would select a filter that resulted in a flow rate within the claimed range. For example, Corson teaches that the flux is 5 to 40 gallons per hour per square feet of filter; if a filter of one square foot were used with the method of Corson, the flow rate would be about 0.32 to 2.5 liters per minute. Likewise, the residence time either would have been within the claimed range if the flux taught by Corson was used, or it would have been a matter of routine experimentation to arrive at the claimed residence time. Further, the regeneration of the filter in situ would have been a matter of routine optimization in the method of Corson, who teaches that the filter may be regenerated by treatment with solvents; although Corson does not teach regeneration in situ, one would recognize that the use of a section of a filtration apparatus which has been closed to the rest of the system, such as that used in the reference, could have been used to treat a filter with a solvent. One of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings discussed above because the purification of streptomycin using activated carbon filtration was known to be effective, and Dalton teaches a method for filtration using activated carbon. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

14. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

15. Applicant's arguments filed August 19, 2008 have been fully considered but they are not persuasive. Applicant argues that the references do not render the claimed invention obvious because they do not teach the claimed filter cartridge. This is not found to be persuasive because the Shima reference teaches a filter cartridge that may be used for the filtration of liquids and meets all of the limitations of the claims. One of ordinary skill in the art would have been motivated to use the filter taught by Shima in the method taught by the combined references for the reasons discussed above. The claimed invention is therefore rendered obvious by the cited references. Thus, applicant's arguments have been fully considered, but have not been found to be persuasive.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/
Primary Examiner, Art Unit 1651